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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BURKHART, MICHAEL D	

ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
11/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/721,532	ERBACHER ET AL.	
	Examiner	Art Unit	
	Michael D. Burkhart	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/2/2007 has been entered.

Claim Objections

Claim 37 is objected to because of the following informalities: "growth factor" should be "a growth factor". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-44 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **These are New Matter rejections.**

Amended claims 18 (from which all other claims depend) recites a list of exogenous compounds for intracellular delivery in lines 22-23, and "pharmaceutical compounds thereof". This language thus limits the recited exogenous compounds from any pharmaceutical compound (previously claimed) to pharmaceutical compounds of the recited exogenous compounds (e.g. proteins, nucleic acids, etc.). Thus, the claims have been narrowed significantly in the is respect. The response indicates support for the amendment may be found in certain paragraphs on pages 7 and 8 of the specification. These passages (nor the remainder of the specification) do not recite, or limit, any of the exogenous compounds to "pharmaceutical compounds thereof", but rather state that the claimed compounds, i.e. a cationic cytofectin, may be used in pharmaceutical formulations, such as gels, pastes, creams, etc., or to deliver molecules in gene therapy. In fact, the passages referred to by Applicants disclose that the exogenous compounds recited in claim 18 may be pharmaceutical compounds (page 7, fourth full ¶), rather than pharmaceutical compounds of the exogenous compounds. Therefore, there appears to be no support for the limitation wherein the exogenous compounds are limited to "pharmaceutical compounds thereof", but rather that the invention comprises exogenous compounds that are pharmaceutical compounds. Thus, the amended claims include impermissible New Matter.

Amended claim 39 limits the cell targeting compound of claim 36 to a neutral or negative co-lipid. Applicants point to page 6 of the disclosure for support of the amendment of claim 39. A review of the disclosure as originally filed, including page 6, does not reveal support for any cell targeting compounds that are co-lipids. Thus, the claim contains impermissible New Matter.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This rejection is maintained for reasons set forth in the Office Action dated 12/28/2006, and for reasons set forth below.**

Claim 33 recites the limitation "lipid-like molecule" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. Furthermore, it cannot be determined how close to the original lipid a "lipid-like" molecule must be in order to fall within the scope of the claimed subject matter. Thus, the skilled artisan could not determine infringement of the claim, rendering the metes and bounds of the claimed subject matter unclear.

Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that the scope of "lipid-like" molecule is clearly defined in the specification because "liposome", according to the present invention, denotes a structure comprised of, *inter alia*, lipid-like molecules.

Such is not convincing because the specification merely recites examples of lipid-like molecules (i.e. "such as 1,2-dioleoyloxiphosphatidylethanolamine") in the context of a liposome. This is not a definition of what constitutes a lipid-like molecule in the context of the instant claims (which are not directed exclusively to liposomes), but merely an example of a single species that could be considered a lipid-like molecule. Thus, it provides no help in determining

the metes and bounds of the phrase "lipid-like." Furthermore, applicants response does not address the fact that the limitation lacks antecedent basis.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18-20 and 23-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Milieva et al (J Appl Toxicol., (1995)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sykora et al (Folia Microbiol., (1991)).

Claims 18-20, 23-25, and 27 are rejected under 35 U.S.C. 102(b) as being anticipated by GB1277086.

The above rejections are maintained for reasons made of record in the previous Office Actions dated 12/20/2005, 12/28/2006, 8/3/2007, and for reasons set forth below.

Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) Milieva et al does not teach that the QAS compound was used to transport any ingredients of the Krebs' solution into smooth muscle cells, or used in transfection, and there is no association between the Krebs' solution and the QAS compounds; 2) Sykora et al do not teach that the BDHD compound promotes uptake of any of

the exogenous compounds found in Luria Broth, Sykora et al do not disclose the use of BDHD for use in transfection, Sykora et al do not disclose BDHD is capable of intracellular delivery of exogenous compounds; 3) Sykora et al teach contacting bacteria with only BDHD, not a composition; 4) Sykora et al teaches away from using BDHD to insert a foreign molecule into a cell; 5) the '086 document does not disclose use of the QAS compounds for use in transfection, or in a composition further comprising an exogenous compound capable of intracellular delivery; 6) none of the references teach that the compounds are effective for intracellular delivery of exogenous compounds, as recited in the instant claims.

Regarding 1), 2), 5) and 6), as set forth in the previous Office Actions, the recitation of an intended use for the claimed compounds (i.e. "for intracellular delivery" and "has the ability to effect delivery of said exogenous compound") does not further limit the structure of the claimed compounds. See MPEP 2111.02 and the text from MPEP 2111.02 cited in the Office Action dated 12/28/2006. Because the cited references teach all the structural limitations of the claimed compositions, the claims are anticipated by the references. Further, if applicants believe the prior art compositions, all of which are fully encompassed by the claims, are not capable of performing the claimed intended use, then applicants are encouraged to provide evidence or scientific reasoning as to why the prior art compounds are not so capable.

Further regarding 1), the experiments of Milieva et al on smooth muscle cells were conducted in Krebs' solution for reasons of record, to which the QAS compound was added. Read the legend to Fig. 1 and the Results section beginning on page 220.

Regarding 3), for reasons of record, Sykora et al teach a composition comprising BDHD with both peptides and sodium chloride, both of which are within the scope of exogenous compounds recited in claim 18.

Regarding 4) "teaching away from" is not a consideration in 35 USC 102 rejections, but rather belongs in arguments directed to 35 USC 103 rejections.

Further regarding 5), the '086 document teaches QAS compounds used in conjunction with a carrier, such as ground corn cobs, which comprise carbohydrate (i.e. the plant cell wall) and protein, at the least, both of which are recited as exogenous compounds in the instant claims. See page 2, lines 76-85.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-38 and 40-44 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, and 11-46 of U.S. Patent No. 6,733,777. **This rejection is maintained for reasons made of record in the previous Office Actions dated 12/20/2005, 12/28/2006, 8/3/2007, and for reasons set forth below.**

Instant claim 27 has been added to this rejection because the '777 specification defines the C_8-C_{20}-alkyl recited in claim 1 as referring to, for example, octyl, decyl, etc. (column 3, lines 48-52).

Response to Arguments

Applicant's arguments filed 7/2/2007 have been fully considered but they are not persuasive. Applicants essentially assert that: 1) amendments to the instant claims obviate this rejection; and, 2) a restriction requirement between Group I (methods of delivery) and Group II (cationic cytofectins) in the parent application, which issued as 6,733,777, prevents the instant rejection. The fact that the restriction requirement was vacated in the parent application does not apply as a reason to maintain the instant rejection because the '777 claims were amended to the format of method claims.

Regarding 1), applicants point to no specific limitations in the instant claims that define over the claims of the '777 patent, which encompass the claimed subject matter for reasons set forth previously, and are directed to compounds and methods for *in vivo* and *in vitro* transfection (claims 8 and 10, at the least).

Regarding 2), a review of the '777 claims reveals claims to both compositions (claims 11 and 29-46) and methods (e.g. claims 1-8). Thus, in contrast to applicants assertions, it appears

Groups I and II from above were indeed rejoined in the parent case. All of the issued claims were not amended to be in the format of method claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael D. Burkhart whose telephone number is (571) 272-2915. The examiner can normally be reached on M-F 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael D. Burkhart
Examiner
Art Unit 1633